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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/692,314	08/05/1996	ROBERT N. HAMLIN	910458.CDA	3428
26161	7590	11/05/2003	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110				DYE, RENA
			ART UNIT	PAPER NUMBER
			3627	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	08/692,314	HAMLIN, ROBERT N.	
	Examiner Rena L. Dye	Art Unit 3627	
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
<b>Period for Reply</b>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>04 March 2003</u> .			
2a) <input checked="" type="checkbox"/> This action is <b>FINAL</b> .		2b) <input type="checkbox"/> This action is non-final.	
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>206-220</u> is/are pending in the application.			
4a) Of the above claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>206-214 and 216-219</u> is/are rejected.			
7) <input checked="" type="checkbox"/> Claim(s) <u>206-220</u> is/are objected to.			
8) <input type="checkbox"/> Claim(s) _____ are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:			
1. <input type="checkbox"/> Certified copies of the priority documents have been received.			
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.			
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).			
a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .		6) <input type="checkbox"/> Other: _____ .	

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 206-218 are pending in the present application.

### ***Claim Rejections - 35 USC § 112***

2. Claims 206-214 and 216-219 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In the “Summary of the Invention” in the present specification, Applicant discloses that a tensile layer (including PEEK or PEK) is combined as an outer layer with a chemically and physically compatible adhesion or bonding inner layer (page 2, last paragraph through page 3, line 36). Therefore, Applicant’s specification does not clearly support a layer of PEEK or PEK located as an inner tensile layer, or a different polymeric layer as the outer layer, as would be supported by the present claims. The PEEK or PEEK layer should be claimed as the outer layer, or external to the inner layer, and the second layer recited as the inner layer, as supported by the present specification.

With respect to the recited, “a second extruded layer comprising a second polymer material different from the first polymeric material” recites limitations broader than the disclosed invention will support. Applicant’s specification specifically discloses that the inner layer is a physically compatible adhesion or bonding layer. Therefore, providing a polymeric

material layer different than the first polymeric material layer may not provide the function of an adhesion or bonding layer as supported by the present disclosure. Applicant's claims are recited more broadly than the present specification will support.

3. Claims 206-220 are objected to because of the following informalities: Claims 206 and 220 include improper Markush language. The limitation "selected from a group consisting of" should be rewritten as "selected from the group consisting of" to recite proper Markush language. Refer to MPEP § 2173.05(h) for guidance. Appropriate correction is required.

***Allowable Subject Matter***

4. Claim 215 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and amended to correct the improper Markush language.

The prior art of record fails to teach or suggest a medical balloon catheter comprising a multilayer balloon having an extruded first layer comprising a first polymeric material selected from the group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK), and a second extruded layer comprising a second polymeric material different from the first polymeric material;

wherein the adhesion layer (second layer) is disposed toward the interior of the balloon relative to the first layer, which is disposed toward the exterior.

5. Claim 220 would be indicated as allowable if Applicant amended the claim to correct the improper Markush language.

The prior art of record fails to teach or suggest a medical balloon catheter comprising a multilayer balloon having an extruded tensile layer comprising a first polymeric material selected from the group consisting of polyetheretherketone (PEEK) and polyetherketone (PEK), and a second extruded adhesion layer comprising a second polymer material different from the first polymer material, wherein the adhesion layer is disposed toward the interior of the balloon relative to the tensile layer, which is disposed toward the exterior.

***Response to Arguments***

6. Applicant's arguments filed on March 4, 2003 have been fully considered but they are not persuasive.

In view of applicant's disclosure and the present claims of record, it remains to be the Examiner's position that the rejection under 35 USC 112, 1<sup>st</sup> para. should be maintained. Applicant's specification clearly discloses the PEEK or PEK layer used as an outer tensile layer, which is exterior to an inner bonding, or adhesion layer.

Applicant's arguments found at page 6 of the "RESPONSE" states that "a particular material, PVC, is described as useful in either the tensile layer or a bonding layer". Polyvinyl chloride PVC is among a list of examples including PEEK or PEK that can be used in the tensile layer. The specification describes a balloon having PVC as an inner layer and PET as an outer layer.

It appears that although the present specification supports the use of PVC as a tensile layer material (combined with ABS) or a bonding layer material by itself, it does not clearly support the use of PEEK or PEK in both the tensile layer and bonding layer. The specification clearly sets forth the use of PEEK or PEK as a material having high tensile strength. There is no clear disclosure of PEEK or PEK having adhesion properties suitable for use in the bonding layer of the disclosed invention. Therefore, one having ordinary skill in the art would not associate PVC and PEEK or PEK as functional equivalents in being used as tensile and adhesion layers in the presently claimed invention.

In view of Applicant's amendments to the present claims and arguments of record, Applicant appears to be broadening the disclosed invention in attempting to claim that which he did not have the right to at the time of the filing date.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rena L. Dye whose telephone number is 703-308-4331. The examiner can normally be reached on Monday-Thursday 8:30 AM - 7:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on 703-308-5183. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.



Rena L. Dye  
Primary Examiner  
Art Unit 3627